UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,067	10/09/2003	Mark B. Knudson	11587.1USCA	9479

7590 10/26/2009

R. Neil Sudol
COLEMAN SUDOL SAPONE, P.C.
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER	
STROUD, JONATHAN R	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
10/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/682,067
Filing Date: October 09, 2003
Appellant(s): KNUDSON ET AL.

R. Neil Sudol
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02/19/2008 appealing from the Office action mailed 12/21/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claim 22 appears on page 9 of the Appendix to the appellant's brief. The minor errors are as follows: There is an extra comma after the phrase "...adapted to anchor the conduit in place,, wherein ...".

(8) Evidence Relied Upon

4787899	**Lazarus**
4604762	**Robinson**
5123917	**Lee**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16,18-21,22,24,31,33-36,38-41,43-45,47-51,53-62, 64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lazarus [4787899].

Re claims 16, 22, 47, 56 and 57, Lazarus discloses a conduit comprising a hollow conduit having an interior and an exterior wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place.

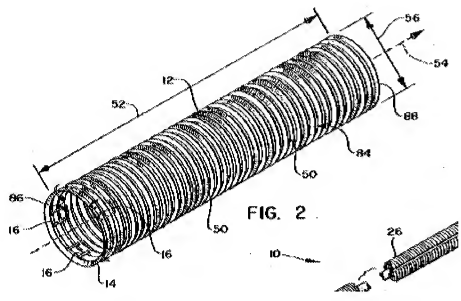

FIG. 2

The language "for use in a wall of a heart" and "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the "bypass conduit" and does not, in itself, serve to further limit the structure of the conduit. Lazarus discloses a conduit that is for use in a lumen (e.g. blood vessel or artery). The properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart. Appellant argues that Lazarus is silent as to the sufficiently rigid to remain open during both systole and diastole. If the vessel of Lazarus did not possess sufficient rigidity, the vessel would collapse and not perform the function of a conduit for blood flow. Though Lazarus is silent as to the rigidity, it appears that when used in the vascular system the vessel remains open during both cycles of the heart.

There is no disclosure in Lazarus which would preclude the use of the vessel in the wall of the heart, and therefor, the vessel of Lazarus is capable of performing the recited function.

Appellant argues that the material of Lazarus is not necessarily material that could remain open in a heart wall during both systole and diastole; however, appellant device utilizes the same materials for the claimed conduit.

Claim 18 is directed to a method step of locating the left ventricle as the chamber. The claim does not further limit the structure or function of the device.

Claim 19, see barbs as illustrated in figures 3 and 4 of Lazarus.

Claims 20, 21, 48, 49, 50, 58, 59, 60, 61, 62, and 64, the function of the barbs, as disclosed by Lazarus, perform the function of anchoring the conduit to a soft tissue. The claims are directed to a method step for locating the anchor to a particular tissue and does not serve as further limiting the structure of the device as claimed.

Claim 24, the claim is similar to claim 16 and is broadly readable on Lazarus. The recitation of "a vessel supporting mechanism does not distinguish over the barbs of Lazarus.

Claim 31, see rejection to claim 21 supra.

Claim 34 and 54, see lumen 12; further, abstract discusses membrane.

Claim 36, the conduit of Lazarus is designed to remain open during both systole and diastole and therefor meets the functional limitation of the claim.

Claim 38, the conduit of Lazarus is deformable so as to conform to the interior surface of the tissue in which it is placed.

Claim 39, the barbs are configured for attaching to the inner surface of the tissue.

Claims 40, 41, 43 and 51 are functional language about the nature of placement, directed to a method, and do not serve as further limiting the structure of the device as claimed.

Re claims 22, 33, 35, 44, 53 and 55, a plurality of rings is seen in fig. 2.

Appellant is reminded that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. MPEP 2114[R-1], citing to In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

Further, in the alternative, the use of 35 U.S.C. 102/103 has been approved by the courts to handle the lack of physical descriptions present in product-by-process claims; if a prior art product is disclosed which reasonably appears to be either identical or only slightly different, a rejection is eminently fair and acceptable; the Patent Office is not required to obtain prior art products and then make physical comparisons therewith. See MPEP 2105.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16,18-21,22,24,31,33-36,38-41,43-45,47-51,53-62 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899] in view of either of Robinson [4604762] or Lee [5123917].

The device of Lazarus does not have additional supporting structures to aid in biasing the conduit to a non-collapsed position.

However, each of Robinson and Lee teach the addition of flexible rings along the length of the conduit to provide strength to the conduit to resist collapsing of the lumen.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Lazarus in view of either Robinson or Lee, in order to provide additional strength, via supporting structures, for biasing the lumen into an open position.

Further, claims 18-21,31,33-36,38-41,43-45,47-51,53-62 and 64, see rejections supra (see 102 rejections under Lazarus) corresponding to the particular claimed subject matter in each claim.

Claims 37,46 and 63 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899], (as rejected under 102(b) above, or in the alternative, as obvious in view of Lazarus and Robinson or Lee), and further in view of Bowen [2127903].

Bowens shows various known configuration of conduits used for augmentation and/or reconstruction of various in vivo tissues, organs and vessels. To form the

conduit of Lazarus in a non-linear conduit as illustrated in figures 6,7 and 7a to better meet the in vivo applications and tissue requirements would have been obvious to one with ordinary skill in the art at the time of the invention based upon routine surgical considerations.

(10) Response to Argument

Appellant's arguments have been fully considered but they are not persuasive.

The language "for use in a wall of a heart" and "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the "bypass conduit" and does not in itself serve to further limit the structure of the conduit, and place no structural limitations on the dimensions and compressive strength of the bypass conduit, as they are an intended use. Appellant is reminded that an apparatus claims must cover what it is, not what it does. See MPEP 2114 [R-1]. ("While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber,* 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)).

Lazarus discloses a conduit that is for use in a lumen (e.g. blood vessel or artery). The properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart.

Appellant contravenes this assertion, saying the dimensions will "usually be so different from the relevant cardiac dimensions that the graft will be unusable for cardiac implantation." But that is irrelevant, as it is directed towards an intended use. There is no structural limitation in the claim that is directed towards the relevant cardiac dimensions; and further, the device can still be placed between the coronary vessel and a chamber in the heart if one so chooses, regardless of suggested efficacy.

Appellant argues that Lazarus is silent as to the sufficiently rigid to remain open during both systole and diastole. If the vessel of Lazarus did not possess sufficient rigidity, the vessel would collapse and not perform the function of a conduit for blood flow. Though Lazarus is silent as to the rigidity, it appears that when used in the vascular system the vessel remains open during both cycles of the heart. There is no disclosure in Lazarus which would preclude the use of the vessel in the wall of the heart, and therefore, the vessel of Lazarus is capable of performing the recited function. Appellant argues that the material of Lazarus is not necessarily material that could remain open in a heart wall during both systole and diastole; however, appellant's device utilizes the same materials for the claimed conduit.

Still further, since a device can be placed where one sees fit, it flows logically that the device could be surgically placed entirely within the body of the heart wall between a coronary vessel and a chamber in the heart. While there may be little motivation to do so, it is fully possible as claimed. The device would then be sufficiently rigid as to remain open during systole and diastole regardless of material properties. Appellant cannot assume that the functional language of the claim will preclude the alternative

placement of the device, regardless of feasibility or reason for doing so. One does not need the motivation, only the ability, to satisfy an apparatus' functional claim language.

Still further, the claims broadly define a "pathway" between the coronary vessel and heart chamber. Thus, the pathway could be a large hole, such that systole/diastole would not close the hole completely, with or without the Lazarus device in place. Thus, the claim's use of "sufficiently rigid" would be satisfied. The claims fail to define tangible physical properties of the device.

Still yet further, appellant argues the dimensions of Lazarus are not appropriate to meet the language "adapted to be position in the heart between a coronary vessel and chamber in the heart." This limitation is broad enough to encompass a device extending from the left ventricle through the wall out to the distal region of a coronary vessel, or a shorter device such as a shunt or stent that extends only from the ventricle to the coronary sinus. This is introduced only to show the relative lack of clarity and broadness of appropriate interpretations in the claimed subject matter.

And even if appellant can properly establish that vessel of Lazarus would not remain open during both heart cycle, appellant has failed to adequately argue the combination of Lazarus in view of Robinson, Lee and Bowen. Each of the secondary references teaches the use of reinforcing members, similar to that as set forth in appellant's own specification. In light of the combination of Lazarus in view of the secondary teachings, the modified vessel would have rigidity beyond that of a corrugated fabric tube.

Appellant argues that there would be no motivation to combine because it would amount to engineering overkill or would not make sense in view of the disclosure of Lazarus. But again, that is erroneous. There is motivation to reinforce these devices in Robinson, Lee and Bowen, and in the art in general. Improving the rigidity of a tubular member is a generally desired quality in these and similar devices. Rigidity is a results-effective variable. Engineering a device "too well" for its intended use inherently reveals a motivation to engineer, or improve, it in the first place. Simply because doing so would exceed the requirements of the original device is not an argument against the motivation for doing so; we look to the motivation to improve indefinitely, not the motivation to achieve only the results of the original device. So, there is sufficient motivation to combine.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Jonathan Stroud

/JONATHAN STROUD/

Examiner, Art Unit 3774

Conferees:

David Isabella

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774

/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775